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TITLE: A Randomized Clinical Trial of the collaborative Assessment and Management of Suicidality vs. Enhanced Care as Usual for Suicidal Soldiers"

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

This Randomized Clinical Trial (RCT) will compare the effectiveness of CAMS versus enhanced Care As Usual (eCAU) in a sample of n = 150 active-duty Army Soldiers who are experiencing suicidal ideation and/or behaviors. Research clinicians for both treatment conditions will be recruited from the Army Research Site (ARS), Fort Stewart, GA, and will be trained and monitored for adherence to their respective treatment condition by the study staff. Participants will be recruited from a number of sources at the ARS to include the behavioral health clinic and the inpatient unit. Approvals from all IRB committees involved in the study have been obtained. Participant recruitment will begin in MAY 2012.

15. SUBJECT TERMS
Suicide Treatment, Risk Management, Suicide Risk Assessment

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INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

This study will investigate the effectiveness of a novel clinical intervention developed by the PI called the Collaborative Assessment and Management of Suicidality (CAMS). CAMS is not a new psychotherapy. Rather, CAMS is a therapeutic clinical framework with a distinct clinical philosophy and a set of structured procedures that enhance the therapeutic alliance and increase treatment motivation in the patient. This Randomized Clinical Trial (RCT) will compare the effectiveness of CAMS versus enhanced Care As Usual (eCAU) in a sample of n = 150 active-duty Army Soldiers who are experiencing suicidal ideation and/or behaviors. Research clinicians for both treatment conditions will be recruited from the Army Research Site (ARS), Fort Stewart, GA, and will be trained and monitored for adherence to their respective treatment condition by the study staff. Participants will be recruited from a number of sources at the ARS to include the behavioral health clinic and the inpatient unit. The goal of this study is to determine if CAMS is more effective than eCAU in reducing suicidal ideation and behaviors, as well as more effective in returning Soldiers to a fully mission capable status in comparison to Soldiers who receive eCAU.

BODY: This section of the report shall describe the research accomplishments associated with each task outlined in the approved Statement of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Provide data explaining the relationship of the most recent findings with that of previously reported findings. Appended publications and/or presentations may be substituted for detailed descriptions of methodology but must be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work must be approved by the Army Contracting Officer Representative. This approval must be obtained prior to initiating any change to the original Statement of Work.

As of Year 1, the research team has been primarily engaged in gaining IRB approvals from each of the IRB committees involved: Dwight D. Eisenhower Army Medical Center (DDEAMC), the Department of Veterans Affairs Veterans Integrated Service Network 19 Mental Illness Reseach, Education, and Clinical Center (VA VISN 19 MIRECC), the University of Washington (UW), and the Catholic University of America (CUA). The research team has been successful in obtaining approval from all of the IRB committees, but this process has taken longer than anticipated and has pushed back hiring and training of staff and therapists and recruitment of participants approximately one year later than initially proposed in the Scope of Work (SOW).

The initially proposed timeline of activities is included below:

Timeline of Study Activities Over Four Years																
	Year 1				Year 2				Year 3				Year 4			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Hiring and training of staff and therapists	X				X				X							
Training of therapists		X														
Recruitment of training cases		X	X													
Supervision of therapists adherence		X	X	X	X	X	X	X	X	X	X	X	X			
Recruitment of clinical trial cases			X	X	X	X	X	X	X	X	X	X				
Baseline assessments			X	X	X	X	X	X	X	X	X	X				
Clinical trial treatment conducted			X	X	X	X	X	X	X	X	X	X	X			
Follow-up assessments			X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data entry and cleaning			X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data analysis					X	X	X	X	X	X	X	X	X	X	X	X
Dissemination of results									X	X	X	X	X	X	X	X

Based on the unanticipated delays in gaining IRB approval, the following table is an updated timeline of the project:

Timeline of Study Activities Over Four Years																				
	Year 1				Year 2				Year 3				Year 4				NCE Year (if needed)			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Hiring and training of staff and therapists	X				X				X				X							
Training of therapists					X	X														
Recruitment of training cases					X	X	X													
Supervision of therapists adherence					X	X	X	X	X	X	X	X	X	X	X	X	X			
Recruitment of clinical trial cases					X	X	X	X	X	X	X	X	X	X	X	X				
Baseline assessments					X	X	X	X	X	X	X	X	X	X	X	X				
Clinical trial treatment conducted					X	X	X	X	X	X	X	X	X	X	X	X	X			
Follow-up assessments						X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data entry and cleaning					X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Data analysis									X	X	X	X	X	X	X	X	X	X	X	X
Dissemination of results													X	X	X	X	X	X	X	X

Although recruitment of the research therapists and participants was unable to be done prior to gaining approval from all of the IRB committees involved in the oversight of the project, the team has conducted bi-weekly conference calls and made several site visits to the ARS to properly set the conditions for the successful execution of the study. Coordination and approvals with on-site Army leadership has been conducted, to include a meeting with the Commanding General of the installation who assured the team that he would provide support for the study if the team met any issues related to the ARS.

Additionally, the team has developed and finalized the baseline and follow-up assessment batteries, as well as the method of conducting on-line assessments with participants. A revised version of the Suicide Status Form (SSF-IV) was developed to support this research, and is in its final phase of development for use with the initial trial participants. An updated and in-depth CAMS protocol and training manual was also created for this project. It is also in its final phase of development for use with the initial trial participants.

Initial members of the on-site study staff were recruited, hired, and trained. The 1.0 FTE Participant Coordinator (PC) is currently finishing in-processing at the ARS and will be fully credentialed at the site. The PC, Ms. Gretchen Ruhe, has been famliarized with the site's policies and procedures prior to the start of the trial in an effort to facilitiate particpant recruitment once that phase of the trial begins. The PC has also conducted intensive training for her position with the UW team and has conducted daily conference calls with the project's recruitment and assessment team.

The task list from the project's SOW is listed below in an effort to provide a task by task status update on progress made in the study, as well as to provide updated revisions to the

anticipated timeline of various tasks. Status updates and revised timelines are included in italics following the original task from the SOW.

Task 1: Prepare study manuals for CAMS and Enhanced Care as Usual (E-CAU) Groups. (Year 1, Months 1-6).

Completed. May need to update these manuals as needed following initial trial implementation.

1a: Review existing written materials regarding CAMS. (Year 1 Months 1-3)

Completed.

1b: Review existing Usual Care Model at **"*Army Research Site" (hereafter referred to as ARS)*** (Year 1 Months 1-3)

Completed.

1c: Regular (e.g., 2 per month) group meetings regarding key manual components (Year 1 Months 1-5)

Completed.

1d: Condense key components and write text of first drafts (Year 1 Months 2-3)

Completed.

1e: Review of drafts by senior research team members, outside experts, and study clinicians for 1) readability, 2) comprehensiveness, and 3) feasibility (Year 1 Months 3-4)

Completed.

1f: Manual revision based upon feedback to produce final version (Year 1 Months 5-6)

Completed.

Task 2: Hire and train study staff; modifications with training cases. (Year 1 Months 1-6)

On-going. Have hired PC and are in the process of hiring the 0.5 FTE study therapist. Due to space considerations, and at the request of the ARS, the study team has postponed the hiring of the other study staff due to space limitations at the clinic. The clinic is scheduled to move to a new, larger space, in Fall 2012, where space limitations will not be an issue. Additionally, due to not receiving all IRB approvals until MAR 2012, the team has delayed hiring study staff as no participants could be recruited prior to those approvals.

2a: Select or hire Participant Coordinator (PC), and study therapist FTE to supplement existing *ARS* staffing for study. University of Washington (UW) Co-PI and Research Coordinator (RC) hire research assistant (RA) for follow-up assessments. (Year 1 Month 1-3)

PC has been hired. 0.5 FTE study therapist is being recruited and interviews are on-going. The UW RA has been hired.

2b: UW CO-PI and RC train PC and RA in human subjects and other research protections, study policies and procedures, and administering study assessments. (Year 1 Month 2-3)

Completed.

2c: UW Co-PI and RC train ***ARS*** PC in recruiting procedures and develop adaptations to fit *ARS* context and environment (Year 1 Months 1-6)

Completed

2d: Study therapists are matched to treatment condition and PI and CUA staff train CAMS therapists in CAMS as well as human subjects and other research protection and study policies and procedures (Year 1 Month 3)

Will be completed in the 1st quarter of Year 2 (therapists have been recruited and matched to treatment condition, and the initial training is scheduled for MAY 2012).

2e: PC begins recruitment and assessment procedures for training cases in CAMS. UW staff work with PC on effectiveness of recruitment procedures in ***ARS*** context and develop adaptations as needed prior to RCT cases. (Year 1 Month 3-6)

Will begin participant recruitment following the therapist training in the 1st quarter of Year 2.

2f. CAMS and E-CAU clinicians receive training with draft version of manuals and provide feedback to senior research team members (Year 1 Month 3)

Training is currently scheduled for 29 APR – 02 May. The research team anticipates feedback following the training and further feedback as required during the initial implementation of the study.

2f: CAMS study therapists see training cases with supervision and adherence ratings from PI and CUA staff. Modifications to CAMS appropriate to ***ARS*** context are identified, implemented, and codified in supplementary manual for clinical trial (Year 1 Month 3-6)

Currently scheduled to begin on 07 MAY, the week following the research therapist training by the CUA team.

2g: Enhanced Care as Usual (E-CAU) study therapists see training cases to pilot the intervention. Modifications to E-CAU appropriate to ***ARS*** context are identified, implemented, and codified into E-CAU treatment manual. (Year 1 Month 3-6)

Currently scheduled to begin on 07 MAY, the week following the research therapist training by the CUA team.

2h: UW RA begins follow-up assessments with training cases and UW Co-PI, and RC (with consultation from PI, co-PIs, and statistical consultant) develop any modifications to the tracking and assessment procedures, if needed. (Year 1 Month 4-6)

Anticipated to begin in JUN 2012, the 1st quarter of Year 2.

2i: UW Co-PI and Denver VA MIRECC Co-PIs (with consultation from PI, ***ARS*** Co-PIs, RC, PC, and statistical consultant) evaluate feasibility and value of assessment battery as implemented with training cases and make needed changes in format, length, etc. to assure a viable assessment battery is established (Year 1 Month 3-6)

Anticipated to begin in JUN 2012, the 1st quarter of Year 2.

2k: Final versions of CAMS and E-CAU manuals reviewed with study clinicians (Year 1 Months 5 -6)

Anticipated to be complete during the 2nd quarter of Year 2.

Task 3: Implementation of clinical trial and follow-up of Soldiers of Concern (SOC) (Year 1 Month 7 through Year 3 Month 12)

Will begin during the 1st quarter of Year 2 (May 2012).

3a: PC recruits study participants and assures fast and efficient randomization and matching to study therapists for first session (Year 1 Month 7 through Year 3 Month 12)

Will begin during the 1st quarter of Year 2 (May 2012).

3b: CAMS and E-CAU therapists follow their respective manuals to treat randomized participants (Year 1 Month 7 through Year 3 Month 12)

Will begin during the 1st quarter of Year 2 (May 2012).

3c: UW team conducts follow-up assessments ***using the University of Washington Risk Assessment Protocol (UWRAP) to address suicide risk during follow-up*** *(*Year 1 Month 8 through Year 4 Month 12).

Will begin during the 2nd quarter of Year 2 (AUG 2012).

3d: ***PI and CUA staff will*** conduct ongoing adherence evaluation of CAMS study therapists and provide feedback and supervision to assure CAMS therapists remain adherent— ***consultation by MIRECC Co-PI's will be used on complex cases (e.g., TBI and PTSD)*** (Year 1 Month 7 through Year 4 Month 3).

Will begin during the 1st quarter of Year 2 (May 2012).

3e: With consultation from statistical consultant, ***the UW site*** establishes final database systems and data entry and cleansing procedures appropriate to data collected. ***All pre-treatment and adherence data will be transported by HIPAA secure means to UW site to be entered and maintained.*** Data entry occurs in an ongoing basis (Year 1 Month 7 through Year 4 Month 12).

Will begin during the 1st quarter of Year 2 (May 2012).

3f: With assistance of the PC and *ARS* co-PIs establish and implement procedures for reviewing Army records for study participants and extracting this data ***which will be transported by HIPAA secure means to UW site. This data will be matched to study collected data in consultation with UW PI and statistical consultant.*** With consultation of PI, Co-PIs, and statistical consultant, the data and procedures used to extract medical records will be reviewed and modifications made, if needed, to assure viable data extraction access and procedures are established (Year 2 Month 1-12).

This process is on-going and the initial policies and procedures that have been established in coordination with the Army personnel at the ARS will be updated as required during the implementation of the study.

The following tasks are currently anticipated to begin as scheduled during Years 2-4.

Task 4: Hiring and training of additional or replacement staff, if needed (Years 2-4)

4a: PI provides CAMS training to any additional or replacement CAMS study therapists, if needed, to assure sufficient flow through clinical trial (Year 2 Month 1 and Year 3 Month 1). Supervision of CAMS therapists will continue. (Year 2 Month 1 through Year 4 Month 3).

Task 5: Data analysis and dissemination of results (Years 3 and 4)

5a: Aim I: In consultation with PI, Co-PIs, and statistical consultant, Denver VA MIRECC Co-PIs will analyze data from ongoing follow-up of suicidal individuals enrolled in trial and Soldiers of Concern (who did not report suicidality) to establish a recommended assessment battery from the briefest possible screening tools through an expanded assessment. Data will be compared with that collected in Army record to evaluate the reliability and validity of Army measures as compared to full research battery. (Years 3 and 4)

5b: Presentations, reports, publications prepared reflecting analyses of Aim 1 (Years 3 and 4)

5c: Aim II: In consultation with PI, co-PIs, and statistical consultant, Denver VA MIRECC Co-PIs will analyze clinical trial data to evaluate effectiveness of CAMS from hypotheses (Year 4)

5d: Presentations, reports, and publications will be prepared reflecting the clinical trial results of Aim II hypotheses. (Year 4)

KEY RESEARCH ACCOMPLISHMENTS: Bulleted list of key research accomplishments emanating from this research.

- The research team has finalized a new version of the Suicide Status Form (SSF) to be used in this study, the SSF-IV. The SSF is the primary clinical tool used in CAMS for assessing, managing, treating, and tracking suicidal risk in patients.

- The research team has developed a revised manual for conducting CAMS with patients who are suicidal.

REPORTABLE OUTCOMES: Provide a list of reportable outcomes that have resulted from this research to include: manuscripts, abstracts, presentations; patents and licenses applied for and/or issued; degrees obtained that are supported by this award; development of cell lines, tissue or serum repositories; infomatics such as databases and animal models, etc.; funding applied for based on work supported by this award; employment or research opportunities applied for and/or received based on experience/training supported by this award

As the study has not yet recruited any participants and thus has no data to analyze, there are not yet any reportable outcomes associated with this research. Now that IRB approvals have all been obtained, and the team anticipates recruiting the first study participants in MAY 2012, the team expects to have reportable outcomes during the next project year.

CONCLUSION: Summarize the results to include the importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.

As the study has not yet recruited any participants and thus has no data to analyze, there are not yet any reportable outcomes associated with this research, and therefore no conclusions to draw at this time. Now that IRB approvals have all been obtained, and the team anticipates recruiting the first study participants in MAY 2012, the team expects to have reportable outcomes and associated conclusions during the next project year.

REFERENCES: List all references pertinent to the report using a standard journal format (i.e. format used in *Science, Military Medicine*, etc.).

None at this time.

APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

The revised SSF-IV, the CAMS Rating Scale (adherence form), and the updated CAMS training manual final drafts are now completed and will likely be modified by the team as the initial study participants are recruited undergo treatment in the initial pilot phase of the study. Once these key documents are fully and completely finalized, the team will include these documents in the report.

SUPPORTING DATA: All figures and/or tables shall include legends and be clearly marked with figure/table numbers.